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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/186,810	11/05/1998	WENDA C. CARLYLE	1416.25US02	2290

24113 7590 06/25/2002

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[REDACTED] EXAMINER

PREBILIC, PAUL B

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

3738

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/186,810	CARLYLE ET AL. <i>CF</i>	
Period for Reply	Examiner	Art Unit	
	Paul B. Prebilic	3738	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 			
Status			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>25 April 2002</u> . 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4) <input checked="" type="checkbox"/> Claim(s) <u>1,3,4,8-17 and 28-40</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input checked="" type="checkbox"/> Claim(s) <u>1,3,4,8-17 and 28-40</u> are subject to restriction and/or election requirement.			
Application Papers			
9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)			
1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.	

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3, 4, 8-15, and 28-40, drawn to a prosthesis, classified in class 623, subclass 11.11.
- II. Claim 16, drawn to a method of making a cell-coated prosthesis, classified in class 600, subclass 37.
- III. Claim 17, drawn to a method of distributing a medical article, classified in class 206, subclass 438.

The inventions are distinct, each from the other because of the following reasons:

Inventions I or III and II are related as process of making and product made or used. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, as claimed, could be made by a materially different process such as the endothelial cells could be attached via a solution thereof or individually, or alternatively, undifferentiated cells could be attached to the substrate and then caused to differentiate into endothelial cells.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product could be used in a materially different method such as being made fresh and aseptically before surgery and then used immediately without the need for a package.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

There are three species groups. Applicants are required to select one species from each species group for examination.

Species Group 1 (substrate types)

- A.) Tissue substrate (claims 8-10, 29 and 35)
- B.) Synthetic or bioresorbable material (claims 11, 12, 30, 31, 36, and 37).

Species Group 2 (association types)

- a.) Antibody-antigen
- b.) Protein-receptor
- c.) Enzyme-substrate

Species Group 3 (prosthesis types)

Select one of the prosthesis types listed in claim 15 for examination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable. Currently, no claims are generic because of claim 15. Claim 15 has elements that are not true prostheses such as sutures, pledgets, electrical leads, percutaneous devices, and AV shunts. They are not prostheses because they do not replace a missing or defective part of the body. An amendment to claim 15 or clarification thereof is respectfully requested in response to this Office action.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Due to the involved nature of the restriction requirement, the Examiner decided to mail out the restriction rather than try to explain it over the phone to the Applicants.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738